

RESEARCH ON THE USE OF OXYTETRACYCLINE IMMERSION THERAPY TO CONTROL BACTERIAL DISEASE IN COOL AND WARM WATER FISH

Aquaculture America 2003
Louisville, Kentucky

Need and Funding

- Immersion therapy would be useful for fish that do not or will not eat prepared diets
- Multistate Conservation Grant funded through IAFWA (3 years)



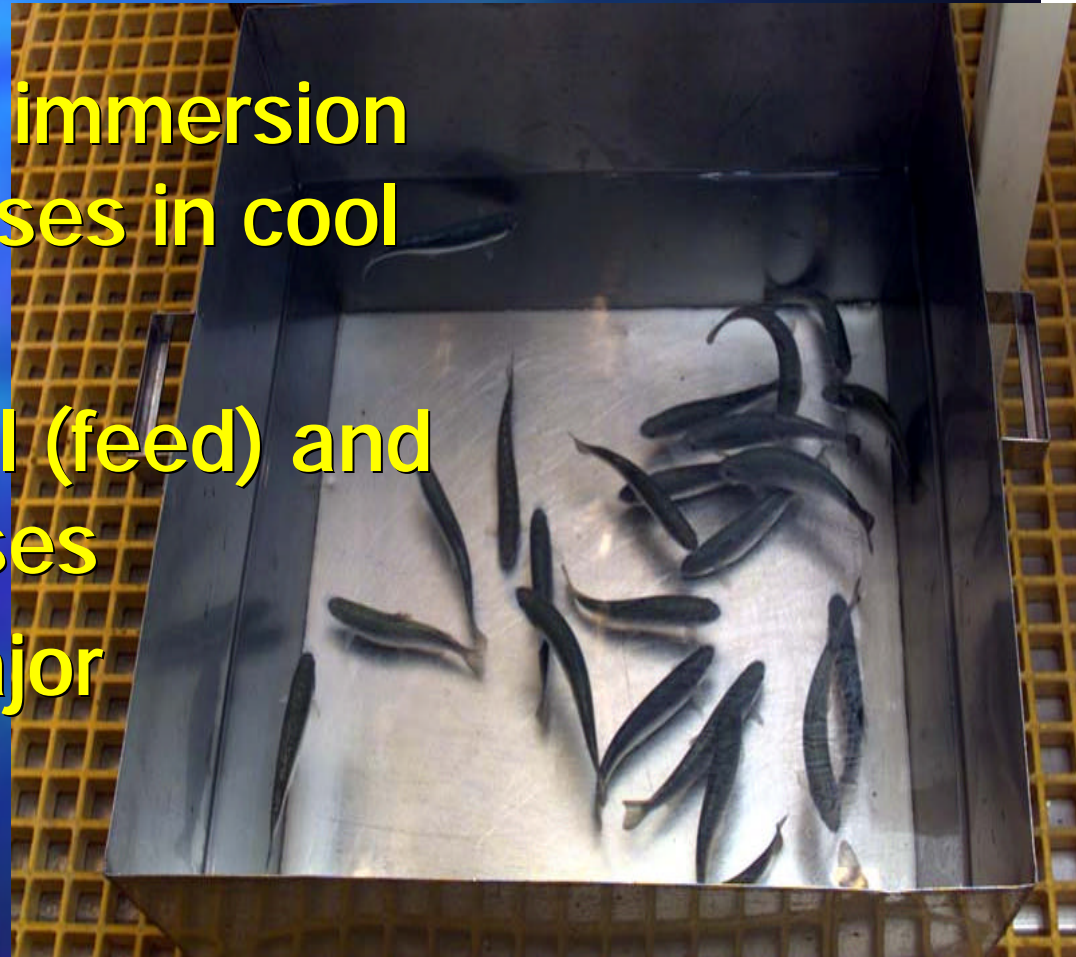
Technical sections required for an approval

- Product Chemistry
- Efficacy
- Target animal safety
- Mammalian toxicology
- Human food safety
- Environmental safety



Objectives of project

- Seeks approved use of immersion OTC for bacterial diseases in cool and warm water fish
- Data available from oral (feed) and immersion (marking) uses
- Efficacy data will be major requirement



Hatchery survey

- Web based survey conducted in 2000
- 22 hatcheries indicate interest in use of OTC immersion therapy
- Most hatcheries indicate they would use 10-20 mg/L for 1 to 3 days

Completed and planned studies

STUDY PLAN

- Data call-in
- Develop and validate analytical method
- Pivotal efficacy
- Pilot studies to mitigate discharge
- Assessment of dosage and residue levels

Data Call-In

- Data call-in for all holders of INADs for OTC Immersion (2002)
- Summary report submitted to Center for Veterinary Medicine Oct. 2002
- Contains supplementary data mostly for white sturgeon and escocids

Analytical method

- Pivotal (well controlled) efficacy trials require analytical verification of dose
- Validation of method; must be acceptable to CVM
- Study protocol reviewed by CVM and study under way

Pivotal efficacy

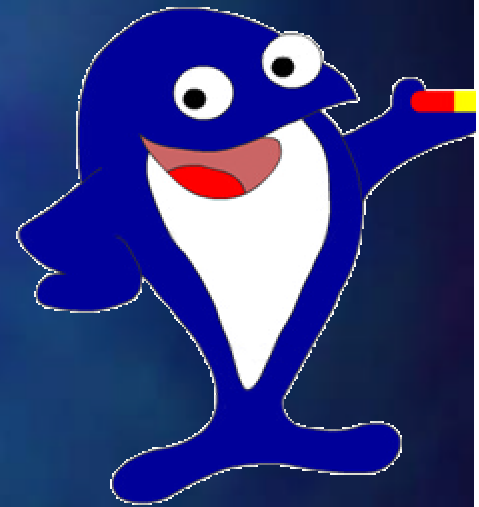
- Pivotal efficacy trials planned over next 2 years
- Targeting bacterial disease in cool and warm water fish
- Trials require replicates of treated and control groups

Discharge

- Practical methods for removal of OTC from bath water
- Can avoid additional environmental safety requirements if OTC is removed
- Adsorbed to charcoal, clay or divalent ions; degradation with temperature or pH

Assessment of dosing and residue levels

- Generally assumed OTC immersion only effective for external infections
- Some assessment of residue levels at different doses will be made for effectiveness on systemic bacterial diseases



Summary

- Efficacy data call-in submitted to CVM likely contains only supplementary data
- Analytical method validation to verify dose in efficacy trials
- Plan to conduct pivotal efficacy trials
- Assess mitigation and concentration in fish tissue